FEB 1 4 2000

K993037

GE Medical System
P.O. Box 414, W-709
Milwaukee, WI 53201
USA

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: 31 August, 1999

Identification of Product: LCV+ Version 2
Classification Name: Solid State X-ray Imaging System
Manufacturer: GE Medical Systems S.A.-Europe
283, rue de la Minière
78530 Buc, France
Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The **LCV+ Version 2** is substantially equivalent to the currently marketed **LC** cardiographic system (K890348), which complies with the same or equivalent standards and has the same intended uses. The digital sub-system, called **DL,** is substantially equivalent to the fluoroscopic digital equipment **DLX** (K926258 and K945459).

Device Description: The **LCV+ Version 2** is designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a fiber channel link to an acquisition equipment then to a network (using DICOM) for applications such as post-processing, printing, viewing and archiving. **LCV+ Version 2** consists of a cardiac monoplane positioner, a vascular table, an X-RAY system and a digital detector.

Materials: All construction and materials are compliant with UL 187 for the existing components and with UL2601, IEC 601-1 and collateral standards for the new components.

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Design: There are hardware and software redundancies to prevent single point failures that could cause unintended motion.

Energy Source: 360V to 480V AC, 50/60Hz.

Indications for Use: The **LCV+ Version 2** is indicated for use in generating fluoroscopic images of human anatomy for cardiology diagnostic/interventional procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology.

Comparison with: It is the opinion of GE Medical Systems that the **LCV+ Version 2** is of comparable type and substantially equivalent to an Advantx Cardiography System **LC** (K890348). The **LCV+ Version 2** presents no new safety concerns. This system will comply with the x-ray requirements of 21CFR as well as the safety requirements noted above.

Summary of Studies: Six **(6)** cardiologists from two **(2)** hospitals compared digital and image-intensifier recorded images from 31 pairs of patients, and found that the digital images had equivalent image capability.

Conclusions: GE considers the **LCV+ Version 2** to be equivalent with the predicate device. The **LCV+ Version 2** provides recorded fluoroscopic sequences that result in diagnostic capabilities equivalent to Image Intensifier images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- Hazard identification (Attachment 8)
- Risk evaluation (Attachment 8)
- Software Development and Validation Process (Attachment 7)
- External validations of paired sets of Image Intensifier image and digital images by two research hospitals to assess the diagnostic equivalence of the digital images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2000

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K993037
LCV+ Version 2 System (SSXI Fluoro Device)
Dated: December 21, 1999
Received: December 22, 1999
Regulatory class: II
21 CFR 892.1650/Procode: 90 MQB

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K993037

Device Name: **LCV+ Version 2 System**

Indications for Use

The **LCV+ Version 2** is indicated for use in generating fluoroscopic images of human anatomy for cardiology diagnostic/interventional procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993037